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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,217	05/02/2006	Kevan M. Shokat	18062G-005410US	4581

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,217	Applicant(s) SHOKAT ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Action below replaces the Election/Restriction requirement mailed January 8, 2008.

Claims 1-22 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-19, drawn to a method of mapping a post-translational modification using a protease.

Group II, Claims 20 and 21, drawn to a reactive solid-phase material.

Group III, Claim 22, drawn to a method of immobilizing a post-translationally modified peptide.

For Invention I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-III and, if Invention I is elected, election of Inventions (A)-(AAAA), as indicated below.

If Invention I is elected, elect one amino acid of:

- (A) Lysine residue
- (B) Aspartic acid residue
- (C) Serine residue
- (D) Threonine residue

If Invention I is elected, also elect one side chain of:

For a lysine residue elect one of;

- (E) a carbamate,
- (F) an amide,
- (G) an N-sulfonyl,
- (H) an N-sulphenyl,
- (I) an N-nitro,
- (J) an N-nitroso,
- (K) an N-oxide,
- (L) an imine,

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- (M) an N-alkyl amine,
- (N) an N-aryl amine,
- (O) an N-phosphinyl,
- (P) an N-phosphoryl, and
- (Q) an enamine

For an aspartic acid residue elect one of;

- (R) ester,
- (S) an amide,
- (T) an oxalose,
- (U) an oxazoline,
- (V) a stannyl ester, and
- (W) an hydrazide

For a serine or threonine residue elect one of;

- (X) sodium sulfate
- (Y) cysteamine

If Invention I is elected, also elect one derivatized amino acid of:

For a lysine residue;

- (Z) Lys(Aloc),
- (AA) Lys(Ac),
- (BB) Lys(Boc),
- (CC) Lys(biotinyl),
- (DD) Lys(2-bromo-Z),
- (EE) Lys(2-chloro-Z),
- (FF) Lys(Dnp),
- (GG) Lys(Fmoc),
- (HH) Lys(For),
- (II) Lys(Me).sub.2, Lys(nicotinoyl),
- (JJ) Lys(Tfa),
- (KK) Lys(Tos),
- (LL) Lys(Z),
- (MM) Lys(Z)(isopropyl),
- (NN) Lys(Boc)(isopropyl),
- (OO) Lys(dansyl),
- (PP) Lys(Dde),
- (QQ) Lys(Me).sub.3,
- (RR) Lys(Mtt),
- (SS) Lys(palmitoyl),
- (TT) Lys(TNM),
- (UU) Lys(acetimidoyl),
- (VV) Lys(2,4,-dichloro-Z),
- (WW) Lys(Me),
- (XX) Lys(p-nitro-Z),
- (YY) Lys(5/6 FAM),

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(ZZ) Lys(pyrenebutyryl), and
(AAA) Lys(guanidinylyl)

For an aspartic acid residue;

(BBB) Asp(OBzl), Asp(OcHex),
(CCC) Asp(OtBu), Asp(OMpe),
(DDD) Asp(Ofm),
(EEE) Asp(Osu),
(FFF) Asp(2-phenylisopropyl ester),
(GGG) Asp(ONp)

If Invention I is elected, also elect one protease class of:

(HHH) a serine endopeptidase,
(III) a metalloendopeptidase,
(JJJ) a cysteine endopeptidase,
(KKK) an aspartic endopeptidase
(LLL) a lysine-specific peptidase
(MMM) an aspartate-specific peptidase

If Invention (LLL) is above elected, also elect one protease of:

(NNN) endoproteinase Lys-C,
(OOO) lysyl endopeptidase,
(PPP) trypsin,
(QQQ) plasma kallikrein,
(RRR) oligopeptidase B,
(SSS) tryptase,
(TTT) plasmin,
(UUU) acrosin,
(VVV) granzyme A,
(WWW) yapsin 1,
(XXX) peptidyl-Lys metalloendopeptidase,
(YYY) magnolsyin

If Invention (MMM) is above elected, also elect one protease of:

(ZZZ) peptidyl-aspartate metalloendopeptidase
(AAAA) nepenthesin.

The inventions listed as Groups I(A)-(AAAA)-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I(A)-(AAAA)-III appears to be that they all relate to methods and reagents for analyzing post-translationally modified proteins. However, methods and reagents for analyzing post-translationally modified proteins were known in the art. For example, Pharmacia, Inc teach a reactive solid phase material that would react with the N-terminus of a protein in which the N-

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terminal acyl group had been removed, which anticipates Claim 20. Therefore Groups I(A)-(AAAA)-III share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the methods of Groups I(A)-(AAAA) and III do not use the same reagents or produce the same results and said methods do not comprise all of the methods for making or using the products of Group II. Accordingly, Groups I(A)-(AAAA)-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Searching more than one of Groups I(A)-(AAAA)-III would represent a burden on the Office for the following reasons. Because a search for any one of the methods of Groups I(A)-(AAAA) and III would not encompass a search for the other method because the methods do not share a special technical feature of steps and products used, or results produced. Thus, the search for more than one of Groups I(A)-(AAAA) and III would be a burden on the Office. A search of the products of Groups II would not encompass a search of any of the methods of Groups I(A)-(AAAA) and III, or vice versa, because said methods are not the only methods of making or using said products. Thus, a search of the products of Groups II with any of the methods of Groups I(A)-(AAAA) and III would be a burden on the Office.

These inventions lack Unity of Invention for the reasons given above. Furthermore, each invention has acquired a separate status in the art due to their recognized divergent subject matter and, thus, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and sub-inventions to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official 821.04, Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. In re Ochiai, and In re Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Final Comments

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/

Primary Examiner, Art Unit 1652